

## **REMARKS**

Claims 1-13 are pending in the application. Claim 1 is the only independent claim.

### ***Claims Rejections - 35 U.S.C. § 112***

Claim 10 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner points out that the phrase “or other solidifying material suited to the purpose” renders the claim indefinite.

In response to the rejection of claim 10 under 35 U.S.C. § 112, second paragraph, applicant amends that claim herein to delete the objectionable phrase.

### ***Claims Rejections - 35 U.S.C. § 103***

Claims 1-6 and 13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,908,428 to Scirica et al. in view of U.S. Patent No. 2,581,564 to Villegas.

Claims 7-11 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,908,428 to Scirica et al. in view of U.S. Patent No. 2,581,564 to Villegas and further in view of U.S. Patent No. 3,918,455 to Coplan.

Claim 12 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,908,428 to Scirica et al. in view of U.S. Patent No. 2,581,564 to Villegas and further in view of U.S. Patent Application Publication No. 2004/0260145 by Borst et al.

**Claim 1** Applicant respectfully traverses the rejection of claim 1 as being unpatentable over U.S. Patent No. 5,908,428 to Scirica et al. in view of U.S. Patent No. 2,581,564 to Villegas.

As recited in amended claim 1, an atraumatic surgical needle has two tissue-penetrating needle tips and comprises a tubular metal shaft that is hollow from tip to tip and that has a cylindrical external surface from tip to tip. The shaft has a central portion that is equipped with a hole through which emerges a surgical thread that is anchored inside the needle.

The principal reference relied on by the Examiner, namely, as being unpatentable over U.S. Patent No. 5,908,428 to Scirica et al., discloses a specialized needle that is specifically designed to function with a surgical suturing apparatus (10, Figure 1). The needle of Scirica et al. necessarily incorporates certain structural characteristics that are markedly inconsistent with applicant's claimed invention.

Applicant's claimed atraumatic needle has a *cylindrical external surface from tip to tip*. The external surface of the Scirica needle is *not cylindrical* even in part. Instead, the external surface of the Scirica needle is bowed (see Figures 5-7, 21-23) or arcuate, concave on one side and convex on an opposing side.

Concomitantly, the Scirica needle extends along a *circular arc*, as seen in Figures 21-23, whereas applicant's needle is *straight or linear*. Claim 1 has been amended to incorporate the further description of the needle shaft as being straight or linear. This feature is shown in applicant's drawings and is inherent to a cylindrical surface.

The external surface of the Scirica needle is *not cylindrical from tip to tip* for another reason. As shown in Figures 5-7 of the reference, the needle (200) is provided

with a “first blade receiving recess 216 and a second blade receiving recess 218.” These blade-receiving recesses *interrupt* the external surface of the Scirica needle and *prevent* the external surface from having a cylindrical shape from tip to tip.

The Scirica needle cannot be modified to assume the form of applicant’s claimed needle because the modifications would render the resulting needle unsuitable for the purpose and use contemplated by Scirica et al. A needle as set forth in applicant’s claim 1 could not function with the suturing device (10) of Scirica et al. The Scirica needle *requires a curved* shape, with a *non-cylindrical* external surface including a pair of recesses (216 and 218) that receive needle-engaging edges (184 and 186) of needle-securing blades (158 and 160) (col. 10, lines 29-47).

For the reasons discussed above, one of ordinary skill in the art would not modify the Scirica needle as asserted by the Examiner. To do so would destroy the needle for its intended purpose and use.

Applicant notes that the needle of the present invention is unique. No other hollow two-tipped needle exists like the claimed needle. As discussed above and in prior Amendments, the invention is not obvious from the prior art. Atraumatic needles have been in use since the 1700’s. The Villegas reference discloses a typical atraumatic needle that has a single tip, with a thread emerging from the back end. However, despite the long history of single-tipped atraumatic needles, no one has devised a two-tipped needle like that set forth in independent claim 1.

***Conclusion***

For the foregoing reasons, independent claim 1, as well as the claims dependent therefrom, is deemed to be in condition for allowance. An early Notice to that effect is earnestly solicited.

Should the Examiner believe that direct contact with applicant's attorney would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

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